EXHIBIT 117

Lewis, Marianne (DHS-MCPD)
From: Hillblom, Doug (DHS-MCPD)
Sent: Monday, November 06, 2000 2:49 PM
To: Hinton, Phil (DHS-PSD-ONSITE); Lewis, Marianne (DHS-MCPD)
Cc: Juarez, Jenny (DHS-PSD-ONSITE)
Subject: RE: OIL 137-00 New Medicaid Only AWP Pricing

Importance: Low

The OIL is still in effect until directed otherwise. We will issue new directions when we have been able to address all of the surrounding issues which are still currently under review.

-----Original Message-----
From: Hinton, Phil (DHS-PSD-ONSITE)
Sent: Monday, November 06, 2000 11:51 AM
To: Lewis, Marianne (DHS-MCPD)
Cc: Hillblom, Doug (DHS-MCPD); Juarez, Jenny (DHS-PSD-ONSITE)
Subject: OIL 137-00 New Medicaid Only AWP Pricing

In May of this year, PSD issued an OIL directing EDS **not** to use a new "Medicaid only" AWP pricing provided by First Data Bank(FDB). The Medicaid only AWP was the result of reporting procedures worked out with FDB to correct problems found by a national investigation that found that drug manufacturers were misreprenting the AWP and wholesale acquisition price of certain products(about 400 NDC's). The OIL stated that Governor's office approval would be sought before implementing the new Medicaid oly AWP pricing provided by FDB.

To my knowledge the OIL is still in effect. Is it correct that we are to continue to use standard AWP's and not use the Medicaid only pricing? Is this issue still under review?

CAAG/DHS0076371 [D]

State of California—Health and Human Services Agency

Department of Health Services

7/20

GOVERNOR'S ACTION REQUESTED

Lyd — pls finalize. MV

TO: File

ATTENTION: Susan P. Kennedy
Cabinet Secretary

FROM: Grantland Johnson
Secretary, Health and Human Services Agency

Prepared by: Doug Hillblom, Pharm.D.
Medi-Cal Benefits Branch
657-0539

DATE:

SUBJECT: Change in Prices for Medi-Cal Drugs effective April 2000,

☒ Request for Approval ☐ For Governor's Information

☐ Request for Cabinet Discussion ☐ For Governor's Signature

SUMMARY/PRO-CON ARGUMENTS: As a result of litigation, Medi-Cal's primary drug price reference source has reduced the Average Wholesale Prices for approximately 400 drug products. If implemented, access to these important drugs may be reduced (see attached discussion).

EFFECT ON EXISTING LAW: N/A → due to decreased reimbursement to providers.

ESTIMATED COST: The aggregate savings from implementing the new prices has not been determined.

TIME FACTOR: A decision on whether to implement the new prices is needed as soon as possible.

RECOMMENDATION: The Department advises that the new prices for the identified drugs not be implemented.

APPROVED:

Diana M. Bontá, R.N., Dr.P.H. Director	Date	Susan P. Kennedy Cabinet Secretary	Date
		Michael J. Gotch Legislative Secretary	Date
Grantland Johnson Secretary	Date	Gray Davis Governor	Date

DHS 1049 (4/00)

CAAG/DHS0076372

CAAG/DHS0076372

The Medi-Cal program has an immediate need for a decision on whether to implement a change in drug reimbursement to providers as a result of a recent settlement of a drug price reporting lawsuit. If implemented, Medi-Cal fee-for-service (FFS) provider reimbursement levels will be reduced for certain drugs. The provider categories affected are physicians, clinics, home health agencies and pharmacies.

Background:

First Data Bank is the primary drug price reference source utilized by the Medi-Cal fee-for-service program and essentially all other state Medicaid programs. A recent national investigation by State and Federal agencies revealed a pattern of misrepresentations by some drug manufacturers of the average wholesale prices (AWP) and wholesale acquisition costs of certain products. The basis of the litigation was that the federal Medicaid fee-for-service program was paying excessive prices for drugs based on the manufacturer reported AWPs which were then published by First Data Bank.

It is our understanding that the intent of the lawsuit was to mitigate the potential for excessive profit margin that would encourage physicians to administer drugs as part of patients' routine office visits. This incentive for profit is based on the difference between the manufacturers' inflated AWPs which is the basis for Medicaid reimbursement and the actual cost of the product to physicians or other providers of these drugs.

As a result, the National Association of Medicaid Fraud Control Units (NAMFCU), which conducted the investigation, entered into a settlement agreement with First Data Bank, which affects the manner in which the AWPs are calculated and reported to state Medicaid fee-for-service agencies. The California Attorney General, Medicaid Fraud Control Unit, has been a participant in this legal class action.

First Data Bank's new AWP reporting system, in accordance with the settlement, is based on their survey of drug wholesalers and manufacturer sales to members of group purchasing organizations (GPO) and other purchasers. These GPO's currently appear to include all wholesale prime vendor networks such as California's State contracts and the United States Public Health Services Office of Drug Pricing. The inclusion of these deeply discounted programs in the survey impact the reported AWPs for the drugs by lowering them substantially. Additionally, these AWPs are only reported to state Medicaid agencies and not to other third party payers. These AWPs will also be reported to Medicare carriers in determining Medicare drug allowances. There is no requirement in either the settlement or by the Federal Government that state Medicaid programs implement the new AWPs as the basis for drug reimbursement to providers.

Impact:

CAAG/DHS0076373

The Medi-Cal program has an immediate need for a decision on whether to implement a change in drug reimbursement to providers as a result of a recent settlement of a drug price reporting lawsuit. If implemented, Medi-Cal fee-for-service (FFS) provider reimbursement levels will be reduced for certain drugs. The provider categories affected are physicians, clinics, home health agencies and pharmacies.

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Impact:

Accepting these new AWP's as the basis for provider reimbursement in Medi-Cal is a serious policy consideration. This change would result in dramatic decreases in the reported AWP for approximately 400 drugs - decreases of as much as 80% in some cases. The new AWP reductions apply to drugs which are usually administered in physicians' offices or clinics. However, the same drugs are often administered at patients' homes via pharmacy dispensing and home health care administration. Cancer drugs are included among these 400 drugs as well as a number of blood factors used by those with hemophilia and drugs for inhalation therapy. The aggregate savings to the Medi-Cal fee-for-service program from the new AWPs for these 400 drugs has not been determined.

Following are just two examples of the price differentials between the traditional AWP pricing mechanism and the new mechanism.

Albuterol Sulfate 0.83% 3ml	(Bronchodilator for Asthma and Chronic Obstructive Pulmonary Disease)		
NDC (National Drug Code)		Current AWP	New

CAAG/DHS0076374

49502-0697-03	$30.25	$12.20

Cisplatin 1mg/ml (Chemotherapy for cancer)

NDC	Current AWP	New
50mg/50ml vial		
63323-0103-51	$210.90	$162.64
100mg/100ml vial		
63323-0103-65	$421.80	$321.00

The above examples were chosen at random from the documents provided to the Department from the New York State Attorney General Office.

Concerns:

The Department is concerned that providers affected by the new AWPs may discontinue serving FFS Medi-Cal patients if the new prices are implemented. If this occurs, patients would either not have access to these important drugs or patients would be directed to a hospital to obtain them. The Department has already received correspondence from various advocacy groups such as hemophilia organizations and pharmacist organizations (see Attachment A) expressing their serious concerns over the new AWPs. We have not yet received similar contact from physicians and clinic provider groups.

Department staff recently participated in a national teleconference on this subject involving other state Medicaid pharmacy programs. Most pharmacy program administrators indicated that they were not implementing the new AWPs at this time because of concerns over provider discontinuation and resultant patient access problems. On the other side of this issue, NAMFCU representatives in a letter dated May 18, 2000 challenge the states' assertions that provider access will be negatively impacted by the adoption of the new AWP's. (Attachment B)

For Medi-Cal, a further consideration is that the new AWP's apply only to FFS, not managed care. This could create a discrepancy between FFS patients and those enrolled in Medi-Cal managed care from the standpoint of access to ~~physician-administered~~ medications. An additional impact would be on the Medi-Cal Drug Rebate Program since there would be two different AWPs used as cost bases for reimbursement, compounding drug rebate disputes from drug manufacturers and affecting rebate collections. As a result of the implications of applying the new AWP's which became available in April 2000, DHS has advised EDS to continue to update the formulary file with the standard AWP's until further notice.

Options:

A) The Department could implement these price changes.
Pro:
The Medi-Cal program would save an undetermined amount of drug cost.

Con:
Providers, may choose not to provide these services to Medi-Cal beneficiaries.
Providers may hospitalize patients to obtain the medically necessary services, resulting in increased program costs.

B)The Department could delay implementation of these price changes until a mechanism has been established to transfer the drug cost savings to increased provider professional fee reimbursement.

CAAG/DHS0076375

Pro:
The Department would lower the risk of decreasing provider participation, by addressing provider reimbursement concerns.

Con:
The Department could set a precedent of transferring savings from one area of provider reimbursement to fund other areas of provider reimbursement.
The Department would not experience the maximum amount of potential cost savings available.

C)The Department could not implement the new price reporting mechanism.

Pro:
This would have the least impact on provider participation and patient access to health services.
No changes would be necessary in the claims processing system.

Con:
The Department would not receive any savings from the decrease in reported AWPs.

Recommendation:

We recommend that Medi-Cal not implement the new price reporting mechanism due to the serious impact on both the providers and beneficiaries.

CAAG/DHS0076376

EXHIBIT 118

EXHIBIT
Abbott 492
PENGAD 800-631-6989

From: David Shepherd [DShepher@dmas.state.va.us]
Sent: Friday, June 23, 2000 3:57 PM
To: Martha.McNeill@tdhex.tdh.state.tx.us
Subject: Re: [NMPAA-talk] NAMFCU Drug Pricing Issue

National Medicaid Pharmacy Administrators

Thank You - David Shepherd - Virginia

>>> Cody.C.Wiberg@state.mn.us 06/22/00 07:09PM >>>
National Medicaid Pharmacy Administrators

Greetings from Minnesota,

Thought I would share with you the text of e-mail that I sent to First DataBank last week:

"I am the Pharmacy Program Manager for the Minnesota Department of Human Services(DHS). As you are aware, First DataBank (FDB) has been working with representatives of state Medicaid Fraud Control Units on drug pricing issues. Since early May, FDB has been reporting to state Medicaid agencies "AWPs" for approximately 428 NDCs that are different than the real AWP that is being reported to your commercial customers. In Minnesota, pharmacy providers are usually reimbursed at AWP - 9% plus a dispensing fee. After checking local wholesale prices, I have discovered that the new "AWP" you are reporting to us is often at or below the actual acquistion cost (AAC) for which pharmacies can purchase the drugs. After subtracting an additional 9%, pharmacies will actually be reimbursed less than their cost for those products - even after adding back a dispensing fee. I have received a number of complaints from pharmacies about reimbursement. Those pharmacies have stated that they will stop supplying the products in question to our recipients if the new "AWPs" remain in effect.
In Minnesota, the reimbursement rate for drugs was established in statute by our legislature. While the legislators did not define AWP, we believe that their intent was to use "AWP" to mean a single estimate of wholesale price as published in a compendia such as Redbook or by First DataBank. My understanding is that FDB is now publishing two sets of "AWPs" for the 428 drugs in question - one for Medicaid agencies and one for everyone else. The fact that the legislators chose to estimate actual acquistion cost at AWP - 9% indicates that they were aware that the single, published AWP was actually higher than the price for which most pharmacies could buy drug products. Had they known that AWP would be reduced to AAC, they would not have established a 9% discount off of AWP.
Consequently, the Minnesota Department of Human Services has determined that we must use the AWPs that FDB is reporting to its commercial customers and NOT the "AWPs" that you are currently reporting to us for the 428 drugs in question. DHS staff intends to bring this issue to the attention of our legislature during the next scheduled session. But for now, I am formally requesting that First DataBank supplies the Minnesota Department of Human

Rodriguez
EXHIBIT NO. 207
10/11/06
G. Barker

Services with the AWPs it supplies to other commercial, non-Medicaid customers as soon as possible. Please feel free to contact me with any questions or concerns."

First DataBank contacted me today and confirmed that they will honor this request. Like many of you, I have spent a considerable amount of time on this issue. (I even spent half of one Sunday in a pharmacy verifying their actual acquisition cost for over one hundred of the drugs in question.
For almost all of those drugs AAC was at or above the new "AWP"). A number of pharmacy providers, ranging from independents to chains to specialty infusion pharmacies have written or called to complain. Many of them called about specific drugs after realizing that they were being reimbursed at less than cost.

There is no doubt in my mind that NAMFCU is correct when it points out that the spread between AWP and AAC is too large for many, even most, of these drugs. The question is - what should be done about it? Almost everyone who is familiar with pharmacy reimbursement knows that AWP "Ain't What's Paid". That's why most states and private pharmacy benefit managers reimburse pharmacies at AWP minus a discount (anywhere from 5-15% or more).
It is also one reason why there is a federal upper limit list and why many states and private PBMs have maximum allowable cost programs. The spread between AAC and AWP is taken into account when determining what to pay for a dispensing fee. For drugs not on the FUL, 42CFR447.331(b) states:

"b) Other drugs. The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under Sec. 447.332 must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of the-- (1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or (2) Providers' usual and customary charges to the general public".

Some public and private third party payers have purposely kept the dispensing fee low precisely because there is a spread between AWP and AAC. In fact, when pharmacy organizations have sought an increase in dispensing fees, the AWP spread has been pointed out to legislators. It is true that ingredient reimbursement is supposed to be based on estimated acquistion cost. The ancillary costs of dispensing the drug are supposed to be accounted for by the dispensing fee. If the AWP spread disappears, the dispensing fee may have to be increased, especially for many of the 428 drugs currently in question. Many of these drugs require some type of compounding or other preparation.

The point, I guess, is that NAMFCU's solution is really a substantial change that may very well have a negative impact on pharmacy providers and, even more importantly, patients. In Minnesota, we believe that something should be done about the AWP spread. However, the problem should be approached in one of two ways:

1. State Medicaid agencies should be allowed to work out their own solutions (by increasing the discount off of AWP, adjusting the dispensing fee, establishing MACs, etc); or
2. A national solution should be pursued that accounts for all aspects of the problem and that is developed by and with input from all interested parties (NAMFCU, HCFA, state Medicaid agencies, private third party payers, First DataBank, pharmacy organizations, etc).

Cody Wiberg, Pharm.D., R.Ph.
Pharmacy Program Manager
Minnesota Department of Human Services

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EXHIBIT 119

UTAH STATE MEDICAID DUR COMMITTEE

THE AMBER SHEET

Volume 9 **Number 2**

April 2001 **Dr. Lowry Bushnell DUR Board Chairman**

Editors: RaeDell Ashley, R.Ph., Duane Parke, R.Ph. An "unofficial" publication of the State Medicaid DUR Board

Pharmacy Manufacturer Direct To Consumer Advertizing →Increased Consumer Pressure on Physicians →Increased Prescribing →Increased Costs → Increased 3rd Party Restrictions→Any Questions? ******

MULTIPLE DISPENSING FEES ASSOCIATED WITH HOME INFUSION PHARMACY SERVICES. The U.S. Department of Justice(DOJ), as part of a legal process, has established a "true" AWP for 437 NDC specific products and has directed the Division to implement this price list. Home infusion pharmacy services have low volume and high expenses. The DOJ's price list places the "true AWP" close to actual acquisition costs, thus eliminating the "spread" or profit that pharmacies have enjoyed for years.

The Division met on several occasions with representatives of the home I.V. infusion specialty pharmacies (infusion committee) subsequent to implementing the DOJ's revised AWP list of the now infamous 437 NDCs. The meetings were productive and resulted in identifying five categorys of difficulty in filling a prescription. Category one is deemed to be the same as those prescriptions normally filled at a typical retail pharmacy. Categorys two through five are increasingly difficult prescriptions with category five being the most difficult and expensive to prepare. Each of the 437 NDCs where placed in a cost category appropriate to the category of preparation difficulty and overhead costs. A new dispensing fee was set for categorys two through five.

- Category five includes chemotherapy I.V.s, pain management, and cardiac ionotropics. Chemotherapy, for example, requires a separate vertical hood and complete gowning to meet OSHA standards which adds considerable expense of time and set-up costs.
- Category four includes complex antibiotics that require laboratory monitoring and reporting.
- Category three includes simple I.V. antibiotics, anticoagulant treatments, I.V. gamma globulin, etc.
- Category two includes nebulizer preparations, growth hormone, etc.

The new dispensing fees are:

Category 2	$ 8.90 J
Category 3	$ 18.90 K
Category 4	$ 22.90 L
Category 5	$ 33.90 M

The original DOJ's 437 NDCs will be linked to their counterparts for other manufacturers Other brands will be reimbursed at the same rate as the DOJ's 437 NDCs. All pharmacies, not jut Home I.V. Pharmacies, will be reimbursed at the same rate for these NDCs. ********

PHARMACISTS - Original Dispensing Fee Restored!! Effective April 1, 2001, the original pharmacy dispensing fee of $3.90 urban and $4.40 rural has been restored.

PHYSICIANS Fee-For Service - At long last, get a 7 ½ % fee increase effective 7/1/01. Remember, you read it here first. This increase may not apply to physicians with HMO contracts.******

Pharmacy -Respiratory Care-Know What Your Numbers Mean* A spirometer measures two numbers that are important for your health care team to determine a variety of lung disorders such as asthma, chronic bronchitis and COPD. These numbers are **FEV_1** (forced expiratory volume in 1 second) and **FVC** (forced vital capacity). More simply stated, **FEV_1** measures how much air someone can breathe out in one second, trying as hard as possible. **FVC** measures the total air volume expelled. In a normal person, the ratio **FEV_1/FVC** is 80% or more. If your number is below normal, consult your primary care provider. *the editors found the above statement without any credit listed and thought it worth passing on. ********

EXHIBIT 120

HOME INFUSION INDUSTRY

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

MAY 5 AND SEPTEMBER 8, 1993

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HOME INFUSION INDUSTRY

WEDNESDAY, MAY 5, 1993

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:30 a.m., in room 2123, Rayburn House Office Building, Hon. John D. Dingell (chairman) presiding.

Mr. DINGELL. The subcommittee will come to order. Today, the subcommittee begins a series of hearings into the high cost, the high growth and increasingly high technology of the home health care industry. While ultimately the subcommittee will examine the whole range of services provided in the home setting, today's hearing provides a special focus on the home infusion industry. This is a multi-billion dollar industry. It targets cancer, AIDS and patients with severe digestive disorders, and a number of other things. In short, these patients tend to be highly vulnerable and largely captive populations.

This is a thriving business. It is fueled principally by three things. First, the continuing concern the Nation feels over restricting patient days in the hospital and federally mandated reimbursement charges designed to bring hospital costs under control; both have helped to foster the growth of this industry. Second, rapidly developing technologies have enabled more flexibility in terms of who can deliver many of these life-saving drugs and services. Finally, there is a growing sensitivity for the seriously ill patient's desire to stay close to their families and to their friends and to maintain some semblance of a normal lifestyle. All of these things have helped promote this business. The industry still has the potential to do all of these things. Unfortunately, the subcommittee is finding that there is a potential for considerable abuse.

Allegations regarding overcharging and an absence of standardized clinical practices, coupled with what appears to be a nearly complete absence of oversight of this multi-billion dollar industry, have helped the subcommittee to come to the conclusion that we must examine in detail the efficacy of existing regulations at both the State and Federal levels. It appears that neither the Federal nor the State regulators nor regulations have kept pace with these burgeoning businesses. They also appear to be among the favorite investments for many physicians, creating the next generation of creatively-designed joint ventures and other financial relationships and incentives that again skew the function of the marketplace and have the practical effect of raising costs substantially over time.

Case 1:01-cv-12257-PBS Document 6465-7 Filed 08/31/09 Page 18 of 26

These services and products range from patients receiving all of their nutritional needs through I.V., to chemotherapy, pain killers, blood transfusions, I.V. antibiotics and more. Many of the therapies available are indeed highly labor-intensive. Even when the patients administer the drugs themselves, ongoing monitoring is critical to the wellbeing of the patient.

Nevertheless, as the Office of Technology Assessment will testify shortly, no one knows just how much we are spending on these services and products and no one has assessed whether the charges are reasonable and whether they are simply outrageous. Many regulators, private insurance carriers and patients themselves believe that the industry is taking advantage of this ignorance to charge whatever the market will bear. There are no standardized mechanisms for reporting, nor are there standardized mechanisms for tracking which services are being provided by whom for billing or for claims payment. The Medicare program has a convoluted system of paying for these services. Some are paid for under Part A, some under Part B. Some are billed as durable medical equipment, some under laboratory services and some under drug provisions. Obviously, it is a situation where it is difficult to keep track of what is going on.

Quality assurance has been left largely to the industry itself, outside the realm of traditional accrediting organizations, peer review and Government regulation. It is clear that this places before us the potential of large risks to many critically ill patients.

These issues are not clear-cut and they are challenging to all. They are certainly challenging to assure that adequate, safe and efficacious care is given. They are also absolutely necessary to be considered when we discuss the possibility of controlling costs in this area. It most be noted that home drug infusion therapy is an important option for patients and could be an important component of cost containment initiatives under any health care reform proposals.

The subcommittee intends to develop a record that helps to ensure that patients receive safe, good quality care at reasonable prices. We are looking forward to working with everyone involved and concerned to accomplish that goal.

The Chair recognizes the distinguished gentleman from Oregon for an opening statement.

Mr. WYDEN. Thank you very much, Mr. Chairman. I want to commend you and the staff for a very important inquiry on an issue that I have a substantial interest in. Sophisticated health services delivered outside the hospital are now the fastest growing sector of American Health Care. Many of these services are virtually unregulated and unaccountable to anyone but the corporate profit bottomline.

My Small Business Subcommittee has been examining these issues as well, Mr. Chairman and we have found the same combustible mix that you have: Fast-changing technology, extremely vulnerable people and indifferent Government regulators. To paraphrase what one expert said about the home health environment, and let me apply it specifically to the matter of home infusion therapy: "The regulatory environment for these services is a little bit like Dodge City before the Marshals showed up."

I think it is absolutely critical that there be basic protections put in place for consumers. I would like to note, Mr. Chairman, that, as part of the Reconciliation Bill, we are going to have the opportunity to put in place some restrictions on physician referrals to these facilities that they own. I think it is very important that there be some basic standards on these physician referrals. I would like to say that I hope our committee looks particularly at putting restrictions on these referrals to home infusion therapy programs where antibiotics and chemotherapy are involved, because there are extraordinary sums of money involved in those two areas. I think the area is very rife with abuse and questionable billings.

I look forward to working with you and our colleagues in pursuing these issues and want to associate myself with your opening remarks.

Mr. DINGELL. The Chair thanks the distinguished gentleman from Oregon for his very helpful opening statement. The Chair is aware of the good work done by the gentleman at an earlier time on another committee and wants to thank hirn for assisting us in this matter.

[The prepared statement of Hon. Marjorie Margolies-Mezvinsky follows:]

STATEMENT OF HON. MARJORIE MARGOLIES-MEZVINSKY

Mr. Chairman, thank you for calling this hearing today to allow us the opportunity to look into one of the fastest growing segments of the health care industry—home infusion. When home infusion became a viable treatment option in the late 1970's, it was heralded as a humane way to treat long-term illnesses, allowing patients to receive therapy at home, and was thought to be an effective way to reduce the enormous costs of in-patient treatment at hospitals.

In some ways home infusion has been a blessing to patients with long-term care needs. They are able to receive their treatment at home, with their families. Family members and patients are trained in basic self-care techniques, taught how to treat bandages as well as how to administer drugs. Patients are able to enjoy direct family support and care so that their emotional needs can be taken into account while their physical needs are met.

In other areas, home infusion has not been as successful. Quality of care is often questioned, oversight into treatment is often lacking, and costs sometimes spiral, virtually unchecked.

As we debate our country's health care problems, and our desire to provide quality care to people at reasonable prices, we must consider all options. Home infusion has the potential to contribute to meeting our health care needs, it has the unique ability to keep the patient at home with family or friends for loving support, and it has the potential to reduce the costs involved with long-term care. It is not only more humane, it has the potential of being more cost effective.

I hope that one of things which comes out of today's hearing, and through future work in this area, is that we can retain the good components of the industry, while eliminating the questionable for the benefit of all of us.

Mr. DINGELL. The Chair announces that panel No. 1 this morning, of the three panels, will be Ms. Marie Kostos-Weber, of 2504 Euclid Heights Boulevard, Cleveland Heights, Ohio 44106. Ms. Kostos, would you like to come forward, please.

The Chair advises that it is the practice of this subcommittee that all witnesses testify under oath. Do you have any objection to testifying under oath? The Chair advises that, under the rules of the House, it is your right to be advised by counsel, if you so choose. Do you wish to be advised by counsel? The Chair advises that copies of the rules of the House, rules of the subcommittee, rules of the full committee are there at the table before you to in-

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[Witness sworn.]

Mr. DINGELL. We thank you very much for being present. The Chair would like to express particular pleasure at the assistance of the Office of Technology Assessment. As you know, I am a member of the board, and take vast pride in the good work that is done by the office. As you very well know, I maintain a strong continuing interest, not only in the welfare of that institution, but the wellbeing of its extraordinarily fine staff. So, welcome. You may proceed with your testimony.

TESTIMONY OF ELAINE J. POWER, SENIOR ANALYST, HEALTH PROGRAM, OFFICE OF TECHNOLOGY ASSESSMENT

Ms. POWER. Thank you very much for your kind comments, Mr. Chairman.

I am Elaine Power. I am a Senior Analyst in the Health Program at the Office of Technology Assessment. My remarks today are based on OTA's study of home drug infusion therapy under Medicare, which was completed in May 1992. The purpose of that study was to examine the implications of Medicare coverage for drug infusion therapy at home. The study did not look specifically at the home administration of intravenous nutrients, because Medicare already covers parenteral nutrition under the Part B prosthetic device benefit. Most of my remarks will relate specifically to drug infusion therapy. I will list my major conclusions first that are relevant from that report, and then add as much additional detail as time allows.

The first and perhaps most important conclusion of the report was that high quality home infusion therapy can and has enhanced the lives of many patients.

Second, the home infusion industry is characterized by a great diversity in the size, the ownership and the scope of infusion and other home services that are offered directly by the provider.

Third, there is little direct Federal regulation of home infusion providers. At least two States do directly regulate home infusion providers, and many other States have some standards that are relevant to infusion pharmacies and the general qualifications of health professionals such as nurses and pharmacists. These do not usually address the broad range of specific practices involved in infusion therapy directly. Two private organizations offer voluntary accreditation to home infusion providers.

Fourth, there is considerable variation in how charges for home infusion are billed and how they are paid by insurers. Whether home infusion therapy is less expensive to a particular insurer than hospital care, and how much less expensive it is, depends in part on how successful that insurer is at negotiating a payment rate with the provider that is less than full billed charges.

Fifth, Medicare has no explicit benefit that covers home drug infusion therapy. Components of this therapy are sometimes covered through various existing Medicare benefits. Because this coverage is fragmented, the amount that Medicare spends on home drug infusion therapy is unknown, and the quality of the overall infusion-related services received by Medicare beneficiaries cannot be evaluated or monitored.

Finally, the lack of reliable outcome standards by which to judge the quality of home infusion therapy that is provided and the lack of guidelines for physicians and other professionals regarding the appropriate course of care for specified subgroups of home infusion patients also hampers the assessment of the quality of home infusion therapy.

The home infusion industry itself is very diverse. Providers include national infusion companies, hospitals, home health agencies, community pharmacists, physician-owned companies, medical equipment suppliers and even some public health departments. Most of these providers follow a home infusion model in which the patient or the patient's family is taught the basic infusion skills. Supplies and equipment are delivered to the patient's home, and a nurse comes in 2 or 3 times a week to check the patient and change the patient's catheter if the patient has a peripheral catheter. Some providers have the patient come into a clinic for nursing services and to pick up supplies. A few actually do all of the infusions in the clinic as well.

There is also great diversity among providers in the scope of infusion related and other home services they provide. There are a few providers that offer both home infusion and other home health services directly. For example, some very large home health agencies that have their own in-house pharmacy or a contract with the pharmacy.

Many other providers offer the broad scope of infusion-related services, but not other home health services. This includes, for example, some of the national infusion specialty companies. Still other providers, which probably make up a substantial proportion of the industry, although there are not any exact numbers, offer one or two components of home infusion therapy directly, and contract or arrange for the other components. For example, it is common for a community pharmacy in one local area to provide the drugs, the supplies perhaps and the pharmacy-related services directly, but contract with or arrange for a local home health agency to perform the necessary nursing visits and other nursing services.

There are no Federal Medicare regulations or any other Federal regulations, as far as I know, that define a home infusion provider or regulate its activities directly. Medicare regulations do apply to health care providers such as hospitals and home health agencies, of course. Some of these providers also offer home infusion services. None of the Medicare regulations specifically address how those infusion therapies are organized and delivered.

There are some State laws that regulate other aspects of home infusion therapy. These are mostly limited to pharmacy standards. As of 1989, at least 22 States had some kind of pharmacy licensure requirement for pharmacies that prepared drug and nutritional products for home infusion. Most of these licensure requirements addressed only aspects relating to the preparation and labeling of the infusion solution rather than to the broader range of infusion-related services. There are at least two States that are exceptions to these limited regulations and have somewhat more extensive specific regulations pertaining to infusion.

State professional licensing regulations do place some minimum restrictions on the activities that various health professionals in-

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a rate setting structure for health care that some how included this. I just do not know if that is the case or not.

Mr. BROWN. Two more questions, Mr. Chairman. Let me ask—I asked Ms. Kostos-Weber this question with insurance companies. She is paying $90,000 a month before she really knew what she was paying, before the insurance began to run out. If you are—and I do not know a lot about how the process works its way through an insurance company, but you are sitting there at a desk in an insurance company, and this bill comes across your desk that, for one child, in home health care of all things—for one child you are paying $90,000, not for physician services, not for nurses services, but simply for some almost minor pieces of equipment and lots of drugs. Why do insurance companies just roll over and pay that? Why is it in the economic interest of an insurance company to just pay that and not think there is a question about it?

Ms. POWER. I cannot answer that directly from this study. We did a study in 1987 on technology-dependent children and home care for that population. At that time, and again, that was several years ago now, there was a growing interest on the part of insurance companies in doing some kind of case management. I presume that, for the most part, it would be in the interest of the insurance companies to do some kind of case management for a patient that they perceived was going to be incurring high medical expenses over time. Again, I do not know exactly the extent to which insurance companies actually do that, or how widespread it is.

Mr. BROWN. How would you, if you were the Congress, and you had been sitting up here and listening to Ms. Kostos-Weber—I mean it is hard to think, no matter what—not that anybody is guilty until they have been heard from, but how Critical Care can charge those kinds of prices—how should we regulate companies like that? I am not even asking you to make a value of judgment of whether we should or not. You seem reluctant to do that. If, in fact, we should, how should we regulate them?

Ms. POWER. The possibility that we looked into in our report was the context of Medicare. So, that is the context I can speak most easily about. One of the arguments for Medicare coverage—there are certainly plenty you could make, not for Medicare coverage too—one of the arguments in favor of Medicare coverage is that Medicare probably has the market power to be able to set rates and find providers that would accept them. I could imagine that a lot of insurance companies would be happy to have a precedent like that set. When Medicare instituted DRG's, a lot of State Medicaid programs and a lot of private insurers found DRG's a convenient mechanism to start linking their payments to. So, I could imagine something similar happening, if Medicare covered home infusion therapy.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. DINGELL. The time of the gentleman has expired.

The gentleman from California is recognized.

Mr. MOORHEAD. I welcome the witness today. In your view is it true that drug or nutrition therapy administered at home, assuming it is properly administered at home, ought to be cheaper than the same treatment administered in the hospital?

Ms. POWER. Our conclusions in our report were that, on the whole, at least the resource cost to the health care system would probably be less if the family were taking up a lot of the tasks. What historically has made home infusion therapy and other high tech home services economically attractive and sold insurers on the idea that this might be something they would want to start covering was the idea that essentially the family was going to be providing services, or the patient providing their own services, that one would be paying for in the hospital—a lot of the ongoing, routine nursing services.

Mr. MOORHEAD. Is there any reason why home infusion therapy ought to be more expensive than the same therapy administered in a hospital?

Ms. POWER. The circumstances under which it could easily, again, from a resource cost perspective, be more expensive was if the patient, in order to go home, needed a lot of other home care services or had to have a paid nurse because there was not anybody in the home capable of providing or willing to provide the services. So, under those kinds of circumstances, if there were a lot of other paid home health services that needed to be provided, it is possible that home care actually could be more expensive.

Mr. MOORHEAD. It would appear that our former witness is being taken advantage of to a great extent, though. Wouldn't you say that those charges were just outrageous?

Ms. POWER. I could not comment on that, I am sorry.

Mr. MOORHEAD. OK.

What effect has the fact that Medicare and Medicaid does not cover many of the aspects of home infusion had on the development of this particular home infusion industry?

Ms. POWER. For Medicaid, apparently there is not quite the same obstruction—obstruction is not quite the word—there is not quite the same prohibition that stops Medicare from getting into drug infusion therapy, at least directly, because Medicaid programs, for the most part, pay for outpatient drugs. In the case of Medicaid, I imagine that the influences on the industry would mostly be in the area of how much they pay and what they decide to pay for.

For Medicare, the fact that Medicare does not cover it—probably the most significant effect is the fact that there is not any of the overlying Federal regulatory structure that tends to come along when Medicare starts covering something. So, for example, under the Medicare Catastrophic Act, where home I.V. drug therapy was going to be an explicit covered benefit, there were going to be regulations that would have defined what a home IV provider was and what kinds of services they could provide and so forth. So, the fact that Medicare does not explicitly recognize the benefit means that that regulatory structure does not exist at the Federal level.

Mr. MOORHEAD. Did the OTA find any significant examples of cost-shifting by home infusion providers?

Ms. POWER. We did not look specifically at pricing or cost shifting, except in the theoretical sense of what would happen if Medicare, through its market power, were able to negotiate or require very low fees, and the effect—the theoretical effect that might have on cost shifting to other payers or whether that would affect certain providers being cut out of the market somehow because they

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things like magnetic resonance imagining, and found out that those physicians who were owners of those labs or had other financial arrangements, were running up far more services, and it was even more costly than other types of facilities.

So when there is a financial stake in ordering a referral, we find that that indeed does happen. At times I would allow that sometimes it may even occur subconsciously.

Ms. MARGOLIES-MEZVINSKY. You talked about service agreements with doctors. Do doctors typically have multiple service agreements with various infusion companies?

Mr. KOPF. Yes. They could have more than one agreement with one company. Now, what we have generally found in the investigations is that a doctor will not have several contracts with several different companies. It is usually just with one company that they will have several different arrangements, and one company, in fact, has 23 different types of arrangements.

Ms. MARGOLIES-MEZVINSKY. Tell me more about that.

Mr. KOPF. These are different types of service contracts, educational grants, in which there is a fee schedule set out for everything that the physician will do.

Ms. MARGOLIES-MEZVINSKY. But all different?

Mr. KOPF. But all different. It is just a way of circumventing the law. What we found, the basic premise in most of these instances is that the contracts and the agreements are worthless. They are just a way so that the doctor can refer patients to the company.

Ms. MARGOLIES-MEZVINSKY. Absent information on physicians and other health care providers' financial relationships with home infusion companies, won't it be very difficult, if not near impossible, to determine whether we are being overcharged or whether the services and products are being over utilized?

Mr. MANGANO. Yes, I think the answer to that is yes. We need far better information on it. In fact in one of the studies, we believe that therapy, even the intra-dialytic parenteral nutrition therapy, which is the parenteral nutrition therapy that occurs as a patient is being dialyzed for end stage renal disease, that is being reimbursed at the same level as a patient in their home doing it themselves would be reimbursed.

Now, we question whether there is any value to that therapy because it is really a supplement to the diet as opposed to taking the place of the full diet. But even if you could answer the question and say, yes, indeed it is a valuable service, we think it should be reimbursed at a far lower rate, because, one, you can buy the supplies in bulk, you can store them easier at an end stage renal facility, you have got a nurse watching over a number of people, shared equipment, the pumps, the pole, et cetera. The reimbursement rate ought to be much lower.

Ms. MARGOLIES-MEZVINSKY. Thank you, very much, Mr. Chair.

Mr. DINGELL. The Chair thanks the gentlewoman.

Gentlemen, the committee thanks you very much for your assistance.

Mr. MANGANO. Thank you, Mr. Chairman.

Mr. DINGELL. It appears we have a great deal to do here. We will look forward to working with you and to receiving your assistance as matters go forward. I think that we have a great deal to be accomplished before we can say that this is a good situation. Thank you, gentlemen.

The Chair notes that our next panel of witnesses is Mr. Miles Gilman, representing the National Alliance for Infusion Therapy, 1001 Pennsylvania Avenue, Northwest, Washington, D.C. 20004.

We thank you for being with us this morning, Mr. Gilman. Mr. Gilman, it is the practice of the committee that all witnesses who appear here testify under oath. Do you have any objection to doing so?

Mr. GILMAN. No, sir.

Mr. DINGELL. Very well. It is your right, given the fact that you are testifying under oath, to be advised by counsel. Do you so desire?

Mr. GILMAN. No, sir.

Mr. DINGELL. Lastly, copies of the rules of the committee, subcommittee, the House, are there at the witness table in the red and the blue books to advise you of your rights and limitations on the powers of the committee. I want to thank you this morning for your assistance to us and for your appearing here today. It is much appreciated.

If you have no objection, then, to testifying under oath, if you would please rise and raise your right hand.

[The witness was sworn.]

Mr. DINGELL. You may consider yourself under oath. Mr. Gilman. The Chair will recognize you for such statement as you choose to give.

TESTIMONY OF MILES E. GILMAN, ON BEHALF OF THE NATIONAL ALLIANCE FOR INFUSION THERAPY

Mr. GILMAN. Thank you, Mr. Chairman.

Mr. Chairman, my name is Miles Gilman and I am the chief executive officer of HealthInfusion, Inc., a home infusion therapy provider with 40 branches across the country. I am also a clinician by training, as a licensed pharmacist and received a doctorate degree in clinical pharmacy.

I am appearing here today on behalf of the National Alliance for Infusion Therapy, a trade association of national manufacturers and providers involved in the provision of home infusion therapy.

On behalf of NAIT, I am pleased to be able to come before the subcommittee and contribute to the important ongoing discussion about this industry. I think you will find that our policy goals are consistent with the subcommittee's general direction on these issues.

We are eager to work with the subcommittee to develop a fair and reasonable regulatory structure for infusion therapy, one that will provide health care consumers with assurance that they will be receiving good quality care, one that will enable third party providers to understand what they are paying for when they cover infusion therapy, and one that will enumerate quality standards to guide all infusion therapy providers in the provision of care.

The prior hearing on infusion therapy held by this subcommittee highlighted several issues of understandable concern. Let me say at the outset that many of the problems of this industry result

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from the fact that it is under-regulated and not well understood. This is attributable in large part to the rapid growth of the industry over the past 10 years and the fact that it does not fit neatly into traditional categories of health care regulation.

As we now deal with the issues before us, however, we should not forget why the industry grew so rapidly, because infusion therapy has enabled thousands of patients to receive life sustaining care in a quality, effective manner in an environment that is familiar, comforting and healing, their homes. Yes, the problems are real, but so are the indisputable benefits and the potential of this young industry.

Before I describe how I believe this industry should be regulated, I believe it is important to discuss some of the major problems that have resulted from the lack of regulation. The relative youth of this industry and the lack of knowledge on the part of payers about infusion therapy have left with us no standard definition of an infusion therapy provider and no standard definition of how infusion therapy should be provided.

Providers range from specialty full-service providers that can supply all the drugs, nursing and pharmaceutical services, supplies and equipment used in the provision of therapy, to entities that supply only one of these components. The lack of definition, however, enables all such entities to hold themselves out to the world as infusion therapy providers.

Often home infusion therapy is covered not as infusion therapy but under a standard or existing benefit issued by the insurer, such as durable medical equipment, home care or prescription drugs. If, for example, an insurer uses its drug coverage benefit to cover infusion therapy and allows a provider to bill only for the drug and perhaps a few related supplies, then the price the provider charges for the drug would not simply be reflective of the cost of the drug.

All of the elements of care are included in the price of the drug, ranging from nursing care to the overhead attributable to coordinating the care provided to the patient.

I can assure you that the providers do not want to do business in this fashion. However, as the reimbursement system is structured for infusion therapy today, providers often will not be able to cover the costs of their services if they do not include those costs in the price of the drugs and supplies.

When the providers have to bill in this fashion, payers often do not know precisely what kind of care their subscribers are actually receiving. This is a logical by-product of the failure of the government and others to adequately define and cover infusion therapy. We believe strongly that infusion therapy cannot be regulated properly until it is covered properly.

Currently there is no integrated framework for the regulation of home infusion therapy. Medicare's coverage of home infusion therapy is fragmented and illogical. Parenteral and enteral nutrition are covered under the prosthetic benefit device, but other infusion therapies are covered at carrier discretion under the durable medical equipment benefit.

While the planned regionalization of Medicare carriers handling durable medical equipment claims will undoubtedly improve the consistency in how the Medicare carriers cover and pay for non-nutrition infusion therapies, there still remains a serious flaw in the current coverage criteria. Neither the prosthetic device benefit nor the durable medical equipment benefit explicitly recognizes the service components of providing infusion therapy.

HCFA interprets both benefits as only covering the drugs and nutrients, supplies and equipment used in the provision of therapy. Although it is commonly understood that it is the nursing and pharmaceutical services that enable infusion therapy to be provided in a home at all, Medicare's current coverage criteria still do not acknowledge that those services have any role in home infusion therapy.

It is not surprising then that Medicare does not have any standards or requirements as to how those services should be provided. In 1988 Congress enacted a Medicare infusion therapy benefit as part of the Medicare Catastrophic Coverage Act. Prior to the repeal of that act, HCFA developed proposed definitions of participation for infusion therapy providers. If those regulations were in effect today, we would have a general standard definition for infusion therapy providers and a clear description of how a provider should function in providing quality care to Medicare beneficiaries.

If we had those definitions of fair and reasonable, a fee schedule could have been developed that reflects the level of care the Medicare program desires for its infusion therapy beneficiaries. The regulation we now need is simply to reenact that Medicare infusion therapy benefit with the accompanying developmental program standards in the form of conditions of participation.

That benefit would present a formidable model for private payers and for health reform. It would also provide the States with an integrated framework of regulation ranging from organizational requirements to clinical practice guidelines. That could then be incorporated into the regulatory structures.

The potential impact of such mandatory standards on insuring the provision of quality care cannot be overstated. If providers are held to a common set of quality standards, then there can be fair competition on the basis of cost, quality and service.

In addition, the standards will give policy-makers the opportunity to decide what level of care they are willing to purchase for these their beneficiaries. For example, the standards would reflect better whether providers should be completely staffed to provide the fullest possible range of services or whether they can or should use contract professionals.

Some infusion providers have chosen to do the former. They employ not only nurses and pharmacists, but also dieticians, social workers, billing specialists, delivery people, records managers, and other technical or specialty personnel in order to offer a complete range of services.

Of course the costs of having these people on staff adds to the total overhead cost of providing their therapy. The advantage for patients, however, is that all the personnel could possibly need are physically located in one place and they are assured that these people are communicating regularly about their case.

The question then for Congress and for HCFA is what the spectrum of home infusion therapy provides, what services do you feel are absolutely necessarily and which are ancillary. These are the

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Mr. DINGELL. Mr. Patashnik, to you have any comments you would like to add?

Mr. PATASHNIK. I don't have any formal statement, sir.

Mr. DINGELL. Very well.

Gentlemen, in your testimony, Mr. Kavanagh, you lay out that HCFA hopes to bring forward an effective plan to get a grip on durable medical equipment, DME bills. Before we get into that, could you describe to us the analysis that HCFA has done on the home infusion industry?

Mr. KAVANAGH. We haven't looked at the home infusion industry in depth in terms of the durable medical equipment. However, we have done some analysis of how much we are paying for durable medical equipment and specifically about home infusion therapy.

Over a period of years, we have come to the determination that there are certainly problems in the durable medical equipment industry, of which home infusion is a part. That is one of the major reasons why we moved to the four regional carriers, because we can focus their attention on durable medical equipment, and obviously one of the items is home infusion therapy.

In the past, the carriers processed claims not only for durable medical equipment, but also for physicians and most of the emphasis of the carriers was on physician claims, because 95 percent of the claims that they processed were from physicians. So this will put a larger, new emphasis at the carriers on processing claims for durable medical equipment, including home infusion therapy.

Mr. DINGELL. Now, what analysis has HCFA done on the home infusion industry and its billing practices?

Mr. KAVANAGH. We have certainly been working closely with the Inspector General's Office. We have in the past had two carriers that concentrated specifically on parental and enteral nutrition.

They have been gathering data on this industry. It is certainly a growing industry. We are well aware of that from the expenditures of the Medicare program. And we have been watching it very closely, and as I said, we have implemented these——

Mr. DINGELL. Have you done any analytical work on this matter, to find out what they are billing, what their costs and charges are and how they relate one to the other?

Mr. KAVANAGH. Well, as I said earlier, the Medicare program pays based on statutorily prescribed fee schedules, so we don't look across the industry in terms of what they are paying or what other payers are being charged, because we don't pay those rates. We pay based on a fee schedule that actually goes back to charges that were billed to us in 1986. And there are national floors and ceilings to try to make the pricing schedule much more consistent across the country.

Mr. PATASHNIK. I might mention, picking up with what Gary had said earlier, we did see a problem, for example, with supplies being billed in a very fragmented way, and we have now established a package payment that would be billed on a weekly basis. We are doing an analysis of the kind of drugs that were covered under the current carriers, to establish the listing of drugs that would be paid for under the regional carriers.

We are also looking at the area of drugs to see if the wholesale price is inflated. Even though right now our payments for drugs

are less than 30 percent of submitted charges, we want to ensure that, in fact, the average wholesale price that is published reasonably represents current acquisition cost. So we are going to be doing some further analysis of what suppliers and physicians are actually paying for some of these products.

Mr. KAVANAGH. And certainly as the regional carriers develop medical review guidelines, they have been doing extensive analyses of the current practices of the home infusion therapy. That is one of the means they use to establish what the guidelines will be for coverage of these services, starting on October 1.

Mr. DINGELL. Well, the home infusion industry provides an assortment of services. They provide the drugs or the pharmaceuticals. If it is nutrition, they provide the nutritional agents. They also provide the pumps and the devices for getting these materials into the body of the patient.

They provide technicians and pharmacists and oftentimes nurses and doctor supervision and things of this kind, as well as other equipment and sanitation devices and things of this kind; do they not?

Mr. KAVANAGH. That is correct.

Mr. DINGELL. So you have got a whole package. You have told us that you are addressing the question of drug costs, pharmaceuticals. I think that is splendid. But that is only a minute portion or at least a small portion of the overall cost of service of delivery to the patient, isn't this right?

Mr. KAVANAGH. That is correct, but the Medicare program does not pay for many of the services that were discussed earlier for home infusion therapy. We do not pay physicians for their services unless there is an office visit, or whatever, involved.

We do not pay, unless it is a home health agency or a hospice, for a nurse to come in and provide home infusion therapy, because we do not have statutory basis to do so—the home infusion benefit is not a separate benefit under the Medicare program.

Mr. DINGELL. All right. Now you pay under both Medicaid and Medicare, do you not, at HHS?

Mr. KAVANAGH. We pay Medicare. Certainly the States have the authority to pay for home infusion therapy. Our understanding is that, you know, most, if not all, States pay for home infusion therapy under the Medicaid program.

Mr. DINGELL. The State which pays for home infusion therapy ultimately bills the Federal Government for the cost of that particular service, don't they?

Mr. KAVANAGH. That is correct, up to——

Mr. DINGELL. I am trying to understand. Now, you don't pay for all of these services to the deliverer of the service. In some instances, I gather, you might pay direct, but generally you pay through the carriers who administer the program for you, do you not?

Mr. KAVANAGH. In the Medicare program, the carriers make all the payments. We contract with 33 carriers across the country to pay for Medicare Part B services, of which durable medical equipment is one.

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As I said earlier, we are reducing the number of carriers that are going to pay for durable medical equipment, down from 33 to 4, to concentrate their effort on this industry.

Mr. DINGELL. Now, you indicated that many of these payments are done on the basis of a statutory list of prices and costs, is that right?

Mr. KAVANAGH. Statutorily prescribed, based on a formula established in law, that is right.

Mr. DINGELL. Well, the previous testimony which we received gave me reason to think that the carriers who cover this, the charges are all different, and make different payments for different services, don't really know what the charges or how these charges are going to be received and reviewed and paid to them by HHS. We gathered from the testimony that the home infusion suppliers or providers all have different ways of arriving at billing and deciding what charges to make to the sundry patients and carriers who are involved in the payment for the services. This leaves me with the regrettable conclusion that HCFA and HHS don't really have a clear pattern of payments for these kinds of services which work.

I asked you to tell me about the analysis which you had made about billings and payments, and you indicated two things—one was that you had changed the ways in which things were going to be done, pay through four carriers, and that you had a statutory billing system or system of charges which dictated what you do.

I sense that—and I want you to understand, this is what we call oversight here—that we have a system which is moving somewhat more slowly than the times, and that the services which are being given are being billed in ways that don't necessarily compensate anybody fairly, don't look to the interests of the taxpayers, don't look to the interests even of the beneficiaries. And the result is that the whole system seems to need some very substantial review.

Now, do you want to give me a comment on that?

Mr. KAVANAGH. I guess I have several comments on that. One is that I think there was some misinterpretation by earlier witnesses about what the Medicare program pays for and does not pay for. There was some implication that a carrier can sit down with a home infusion therapy company and negotiate a payment amount. That is not correct.

They pay through prescribed fee schedules, both for the drug and for the equipment. So there is no negotiating that goes on in terms of between a Medicare carrier and a home infusion therapy company. That may be the case with private insurers, but that is certainly not the case with the Medicare program.

In terms of paying for fragmented services, as I said earlier, we do not have the statutory authority to pay for home infusion therapy as a provider. We have kind of stretched our authority somewhat to pay for these services under the durable medical equipment benefit, and I think certainly within the context of the health care reform initiative, this is one of the areas that we are looking at.

Mr. DINGELL. I think it is desirable that you should pay for it. I think it may even be desirable that you should pay for it under your durable medical equipment accounts. It strikes me that it may even be desirable that you are stretching the law here a bit so you

can pay for it under durable medical equipment. But it leaves me with the regrettable feeling that with all these things, plus the negotiation which you just mentioned, leave us with a rather distorted and peculiar situation in terms of the payment in which we are not satisfied that anybody's interests are being well-served—the providers, the carriers, taxpayers, HHS, Federal Government, because of the fact that we are paying under a system of schedules, and so forth, that don't even relate to home infusion services. Now, am I right or wrong on that?

Mr. KAVANAGH. Well, I think certainly that is a matter of interpretation, but, you know, we have tried the——

Mr. DINGELL. That is a matter of interpretation. Let's have yours.

Mr. KAVANAGH. I think the four durable medical equipment carriers have tried to spell out much more specifically what is covered, what is not covered, when it is covered. In terms of the payment schedules, you know, we are required by statute to do that and we have been following the direction of the law.

Mr. DINGELL. Of course, we are here soliciting your advice as to what is wrong, what ought to be done, what changes we have to make. It is pretty clear we have a situation which is not working and what I am trying to understand is, how do we find out what we do to make it work.

I ask about analysis. You indicated that no analysis has been made, or at least not adequate enough analysis to advise us today or for HHS to inform us of what it is, in fact, should be done to make this system work to satisfy all the various players and parties.

Mr. PATASHNIK. I think part of the analysis that was done, in fact, has led to the establishment of the regional carriers. It was not done just for home infusion therapy. It was done because we knew that since durable medical equipment was a small part of each carrier's total business, probably less than 10 percent when you include physician and laboratory services, that we would get much more intensive analysis done if we narrow the number of carriers that were providing the benefit under the Medicare program

So I think because we knew there was variation in DME—in home infusion as well as other aspects of durable medical equipment such as oxygen coverage, that we thought we would get much better quality and that everyone, the provider and the beneficiary and the program would be better served by limiting the number of carriers that would be providing this benefit.

Mr. DINGELL. That still doesn't address the question of whether those four carriers are going to pay under any better system or schedule than the 33 carriers are at this particular minute. I am left to the conclusion you are going to have less carriers to supervise, but no better basic structure of payments.

Can you comfort me on that?

Mr. KAVANAGH. Well, I certainly think, you know, we did have a provision in the Catastrophic Coverage Act, which was ultimately repealed, that provided services for home infusion therapy specifically under the Medicare program.

I certainly think the administration is looking at this issue in the context of health care reform and unfortunately I, you know, can't

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Mr. DINGELL. They have not. So they are going to proceed under the old rules, isn't that right?

Mr. KAVANAGH. Under the rules that are currently in place.

Mr. DINGELL. Now, what have you done to address the question of whether these payments are proper? Have you done anything to ensure that the payments are either medically proper, medically necessary, or whether the payments meet some kind of acceptable level of payments which would be proximate cause to the industry generally or what the industry should get with regard to a fair compensation plus a reasonable profit?

Mr. PATASHNIK. Well, essentially we are paying for three aspects of services. We are paying for the drugs where our payment rule generally cannot exceed the wholesale price of the drug and on average we are paying substantially less than the submitted or retail price——

Mr. DINGELL. Well, all right, that is for drugs. I am not about to quarrel about it. But there is a whole panoply of other services that are afforded by these home infusion companies: pharmacists, nutritionists, equipment, delivery charges, monitoring charges, doctor and medical services are associated with this, home nursing services, and things of that kind.

Mr. PATASHNIK. As Gary indicated——

Mr. DINGELL. You have not addressed any of these other things, Mr. Patashnik?

Mr. PATASHNIK. I think our reason for not addressing it is because we are precluded by law for paying for nursing services, for the cost of nutritionists, for other services, unless the patients is covered under a benefit that provides such coverage.

For example, if the patient has received covered home health care or covered hospice care, there is an ability to pay for nursing care. Most of these patients are not receiving benefits under the hospice or home health benefit and therefore we cannot reimburse a beneficiary if in fact they are charged for nursing care.

We do pay for the cost of equipment, the cost of pumps, and we have allowances that, as Gary indicated, that are State-wide allowances with national floors and ceilings. Generally the allowance for most pumps are between $240 and $280 a month.

We have not received any data to indicate that an allowance, in fact, is inappropriate. We have tried to respond when we have gotten intelligence from the Office of the Inspector General, for example, that we might be paying inappropriately for some services rendered in ESRD facilities and for that reason, we are clarifying the rules as to when TPN is a covered service in that setting.

But the base service that is covered through many other third-party payers, that includes nursing care and services of nutritionists and so forth, we have no ability under the current law of paying for.

Mr. DINGELL. All right now, Mr. Patashnik, let us try and focus this a little better. You are aware of the fact that this committee has received testimony under oath that home health care providers tend to bill your carriers for services in ways which compensate them for their services fully, even though there might be some looseness in the way in which the billings are made and in which the billings are paid, are you not?

Mr. PATASHNIK. I heard Mr. Gilman say that. I am curious——

Mr. DINGELL. You heard Mr. Gilman say that and you would have heard other witnesses before the committee earlier at the time we initiated our first hearing on this particular matter. And what that leads me to is a conclusion that perhaps billings are being done just fine under existing rules, but in a way that you or the carriers or the statute or the Inspector General might not necessarily approve. Is that right?

Mr. PATASHNIK. I think that is very possible, Mr. Chairman.

Mr. DINGELL. So that leaves us with a little bit of a problem here. The IG has testified about an assortment of schemes for defrauding the government, and the big question is: What is it that we are going to do, either you through your regulatory authorities at HCFA, or we through our statutory authorities to perhaps suppress just a little bit of the fraud that we are beginning to set in the winds here?

Mr. KAVANAGH. I certainly don't think that many of the fraud schemes that were discussed by the Inspector General are going to be stopped by paying home infusion therapy providers more dollars. I think many of those schemes were certainly fraudulent schemes. When you go around signing up beneficiaries and saying you get free milk, I don't think that is a situation that is going to be resolved by paying legitimate suppliers for all of their services if they are providing those services, so I don't know if that is the way to get at that issue.

Mr. PATASHNIK. I also suspect that no matter what regulations we would issue, that that would not prevent those kinds of arrangements, because essentially those arrangements are not permitted under current law and regulation.

Mr. DINGELL. You are not giving me to understand, Mr. Patashnik, you are just throwing up your hands and saying, this is human nature, boys will be boys, people will have fun and they will steal when they can. That is not what you want me to believe, is it?

Mr. PATASHNIK. No. I think what I am suggesting is it is probably an enforcement, not a regulatory problem and that we need to do a better job of investigating——

Mr. DINGELL. Good law enforcement requires good clear basic statute, doesn't it?

Mr. PATASHNIK. Yes, it does.

Mr. DINGELL. It requires good regulatory action?

Mr. PATASHNIK. Yes, it does.

Mr. DINGELL. And good clear regulations and then good, vigorous law enforcement, right?

Mr. PATASHNIK. That is correct.

Mr. DINGELL. Maybe even a good public hanging from time to time as my old daddy used to say.

Mr. PATASHNIK. That couldn't hurt, sir.

Mr. DINGELL. So we are now addressing your part. You are the guy who issues the regulations, you and Mr. Kavanagh. Now, how are we going to get your part of this equation tended to?

Mr. KAVANAGH. I think we have done a lot in terms of focusing the attention on this issue through the durable medical equipment carriers. I think you are asking for——

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